

REMARKS

Claims 42-49 and 57-73 were pending in the present application. Claims 57-73 have been withdrawn, without prejudice, for Applicants to file in a separate application. Claim 42 has been amended. No new matter has been added.

Information Disclosure Statement

The Examiner contends that the IDS submitted on November 24, 2003 is non-compliant in part under 37 C.F.R. §1.97 because Document 27 was not provided to the Examiner. Applicants disagree. Document 27 was supplied and considered by Examiner Celsa in parent application number 09/353,368. Pursuant to 37 C.F.R. §1.98(d)(1), the IDS submitted on November 24, 2003 properly identified this earlier application, and the earlier application is relied upon for an earlier effective filing date. Applicants are therefore not required to resubmit a copy of the reference. Instead, the Examiner is obligated to consult the parent application for the reference.

Objection to the Abstract

The Abstract has been amended to even more clearly describe Applicants invention. Withdrawal of the objection is requested.

Claim rejections under 35 U.S.C. §112, first paragraph (enablement)

Claims 42-49 have been rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement. Applicants respectfully traverse this rejection. The present amendment focuses (without prejudice) to certain preferred embodiments.

Whenever the adequacy of enablement provided by an Applicant's specification is challenged, the Examiner has the initial burden of giving reasons, supported by the record as a whole, why the specification is not enabling. The enablement requirement is satisfied if a disclosure contains sufficient information such that persons of ordinary skill in the art, having the disclosure before them, would be able to make and use the invention. The legal standard for enablement under §112 is whether one skilled in the art would be able to practice the invention without undue experimentation. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

As an initial matter, the Examiner is asked to acknowledge the very large number of actual, working examples presented in the application. These are illustrative of the breadth of the invention and are supportive of its enablement. Whatever experimentation may be

required is greatly abbreviated by the extensive teachings of the specification.

Experimentation is not undue so long as it is of a routine nature. *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Pat. Off. Bd. App. 1986).

The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

PPG Indus., Inc. v. Guardian Indus. Corp., 37 U.S.P.Q.2d 1618, 1623 (Fed. Cir. 1996) (quotation and citation omitted).

With regard to the enablement determination, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971), is noteworthy:

The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirements of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support.

The law thus requires that the Patent Office accept Applicants' assertion of enablement or provide reasoning and evidence to substantiate doubts of the objective truth of Applicants' assertion. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*,

181 U.S.P.Q. 48 (C.C.P.A. 1974). It is noted that the Action admits that the specification “provides guidance and examples directed to the making and use (e.g. antibiotic) of vancomycin glucose C6 substituted derivatives of [original] claim 83-101 which share a common structure.” (Action, pg. 5).

Given the present claim focus on certain preferred vancomycin glycopeptide embodiments together with the extensive exemplification of the specification, it is submitted that enablement has been shown and that the requirements of the first paragraph of 35 U.S.C. §112 have been met. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 42-49 under 35 U.S.C. §112, first paragraph.

Claim rejections under 35 U.S.C. §112, first paragraph (written description)

Claims 42-49 have been rejected under 35 U.S.C. §112, first paragraph for alleged lack of written description. Applicants respectfully traverse this rejection. The present amendment focuses (without prejudice) to certain preferred embodiments.

The claims have been amended to even more clearly clarify that the present invention encompasses methods for making glycopeptides have a heptapeptide structure of naturally occurring vancomycin. The specification, including the numerous working examples, provides abundant description of the claimed structure and sufficient guidance for carrying out the claimed methods so that one skilled in the art would be satisfied that the Applicants were in possession of the claimed invention at the time of filing. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 42-49 under 35 U.S.C. §112, first paragraph.

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Conclusion

Applicants submit that claims 42-49 are in condition for allowance. An early Notice of Allowance is respectfully requested. If the Examiner disagrees, he is invited to telephone the undersigned.

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